

Appl. No. 09/998,822
Amendment Dated: November 7, 2003
Reply to Office Action of Aug. 25, 2003
Docket No.: MSU 4.1-542

REMARKS

Claims 4 to 12 are pending. Claims 1-3 and 13-32 were withdrawn from prosecution as a result of a Restriction Requirement Under 35 USC 121. No claims are allowed.

Table 1, page 38, was objected to because of the failure to define the symbols. The symbols were for internal reference purposes and have no meaning. Enclosed is a revised Table 1 with the symbols deleted.

The trademarks noted in the application have been capitalized.

Claims 4 to 12 were rejected under 35 USC 112, first paragraph, as being broader than the enabled disclosure. Applicant has amended independent Claim 4 to include the 28, 30 and 32 kDa antigens which were enabled as pointed out in the Office Action. Reconsideration of this rejection is requested.

Claims 4 to 12 were rejected under 35 USC 103(a) as being unpatentable over Applicant's 1992 publications (Mendoza et al, J. Clinical Microbiology, 30/11:2980-2983; Mendoza et al, Micropathologia, 119:89-95).

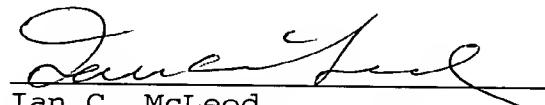
Enclosed is a Declaration under 37 CFR 1.132 which overcomes the *prima facie* obviousness rejection. The rejection is using Applicant's disclosure in the application with his earlier references to link them

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together. One skilled in the art would not have thought to combine the Mendoza et al references, and certainly the results achieved could not have been predicted. Reconsideration of this rejection is requested.

It is now believed that Claims 4 to 12 are in condition for allowance. Notice of Allowance is requested.

Respectfully,



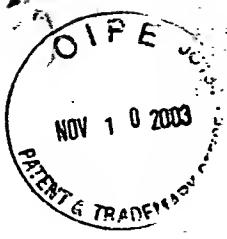
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Enclosure: Declaration Under 37 CFR 1.132
Replacement Page 38 (Table 1)

Table 1. Clinical features of equine cases with pythiosis used in this study and their responses to *Pythium insidiosum*-vaccine

State	Age/sex	Lesions	Duration of illness	Diagnosis	Previous treatments	Vaccination reaction	Outcome
AR (G)	4 y/F	Abdomen, 220X220 mm	4 months	ID, ELISA (+)	Surgery, drugs	Strong, 123 mm	Cured
FL (Sc)	13 y/F	Face, 80X30 mm	>4 months	ID, ELISA (+)	Surgery, Drugs	Mild, 25 mm	Cured
FL (Sn)	12 y/M	Limb, 150X100 mm	>2 months	ID (+), clinical	Surgery	Mild, 60 mm	Cured
FL (Jo)	20 y/M	Limb, 300X150 mm	>2 months	ID (+), clinical	Several surgeries	Mild, 60 mm	Cured
FL (Wa)	8 y/F	Limb, 60X50 mm	5-7 days	ID (+), Clinical	Surgical debridement	Strong, 100 mm	Cured
FL (Ho)	5 y/F	Shoulder & abdomen 50X50 & 120X20mm	15 days	ELISA (+)	Cryosurgery	Strong, 200 mm	Cured
FL (Pe)	22 y/M	Limb, 60X40	17 days	ID, ELISA (+)	Surgical debridement	Mild, 30 mm	Cured
LA (Re)	5 y/M	Limb, 120X100 mm (two lesions)	2 months	ELISA (+)	Surgical debridement	Mild, 90 mm	Cured
MS (Ba)	3 y/F	Limb, 250X250 mm	>2 months	ELISA (+)	Topical drugs	Strong, 150 mm	Cured
MS (Pa)	15 y/F	Limb, 300X200 mm	4 months	ELISA (+)	Topical drugs	Strong, 170 mm	Cured
MS (Im)	2 y/M	Limb, 300X300 mm	4 months	ELISA (+)	Topical drugs	Strong, 200 mm	(Vaccine + surgery) Cured
MS (So)	7 y/F	Limb, 240X240 mm	3 months	ELISA (+), Histopathology (+)	Topical Drugs	Strong, 150 mm	(Vaccine + surgery) sacrificed
NC (Sa)	20 y/M	Inguinal, 60X50 mm (two lesions)	>2 months	ID (+), ELISA (+)	Surgery	Mild, 40 mm	Not cured
NC (Ga)	14 y/F	Inguinal 200X150 mm	>2 months	ID (+), ELISA (+)	Surgery	Mild, 30 mm	Not cured
TN (Re)	4 y/F	Abdomen, 200X80 mm	2 months	ELISA (+)	Topical Drugs	No response	Not cured
TX (Ta)	13 y/M	Limb, 250X100 mm	>4 months	ELISA (+)	Topical Drugs	Strong, 200 mm	Died
TX (Ah)	5y/M	Limb, 280X210 mm	1 month	Clinical, unkters ELISA (+)	Surgery, drugs	Mild, 30 mm	Cured
TX (Co)	6 y/F	Limb, 100X80 mm	1 month	ELISA (+)	Topical drugs§	Weak, 15 mm	Not cured
TX (Sn)	22 y/M	Mouth, 150X100 mm	>2 months	ELISA (+), Histopathology (+)	Surgical debridement	Weak, 5 mm	Not cured



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Declaration Dated: April 15, 2003
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.: 09/998,822

Applicants: Alberto L. Mendoza

Filed : November 1, 2001

Title : VACCINE FOR PREVENTING PYTHIOSIS IN HUMANS
AND ANIMALS

TC/A.U. : 1645

Examiner : Nita M. Minnifield

Docket No.: MSU 4.1-542

Mail Stop Amendment
Commissioner For Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Alberto L. Mendoza, the inventor in the above referenced application, states as follows:

(1) That he is a Professor in the Medical Technology department at Michigan State University, East Lansing, Michigan, and has extensive experience in the treatment of Pythiosis;

(2) That he tested the vaccines presently claimed in the above entitled application as shown by the

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following papers:

- (a) Mendoza, L., et al., Vaccine 21 2797-2804, Elsevier Science Ltd., (2003);
- (b) Santurio, J. M., et al., Vaccine 21, 2535-2540, Elsevier Science Ltd., (2003); and
- (c) Hensel, Patrick, et al., JAVMA, Vol. 223, No. 2, July 15, 2003.

(3) That these papers show that the claimed vaccine is unexpectedly much more effective than his earlier vaccines described in the 1992 Mendoza et al references cited in the Office Action.

(4) That he could not have predicted the results with the vaccines of the claims, and it was not at all obvious to him that such results could be achieved. This was especially true in horses, dogs and humans; and

(5) That the undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the

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Title 18 of the United States Code and that such willful
false statements may jeopardize the validity of the
application or any patent issuing thereon.

Respectfully,



Alberto L. Mendoza
Date: 11/5/03